

## SPIRIT SCIENCES USA, INC

6733 S. Sepulveda Blvd., Suite 108, Los Angeles, CA 90045 TEL: (310) 568-1030 FAX: (310) 861-5612 www.spirit-sciences.com

July 9, 2004

Susan J. Walker, M.D. Director Division of Dietary Supplement Programs Office of Nutritional Products. Labeling and Dietary Supplements (HFS-800) Room No. 4D042 Center for Food Safety and Applied Nutrition Food And Drug Administration 200 C Street SW Washington, DC 20204

Reference: Dietary Supplement Notification Pursuant to 21 C.F.R. § 101.93

Product: RU-21

FDA Registration #: 17007788334

Dear Dr. Walker:

This notification is being submitted in triplicate on behalf of Spirit Sciences USA, Inc., who is the distributor of the product which bears the statements identified in this notification.

Pursuant to 21 Code of Federal Regulations Section 101.93, Spirit Sciences USA, Inc., hereby notifies the Food and Drug Administration that they intend to market RU-21, a dietary supplement product, with labeling bearing statements provided for in 21 U.S.C. § 343(r)(6), section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Spirit Sciences USA, Inc.'s "RU-21®" PRODUCT NAME:

**DISTRIBUTED BY:** Spirit Sciences USA, Inc.

6733 S. Sepulveda Blvd., Suite 108

Los Angeles, CA 90045

MANUFACTURED BY: AMK Market

Dneptropetrovskaya 3/5

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Confidential Under 21 C.F.R § 20.61

Spirit Sciences requests written notification prior to public release of this document.

## Moscow, Moskva 113587 RUSSIAN FEDERATION

DIETARY INGREDIENTS: succinic acid,

fumaric acid, L-glutamine, vitamin C, and glucose (dextrose)

STATEMENTS OF

NUTRITIONAL SUPPORT: \*Promotes morning energy

\*Supports health and vitality

\*Supports the body's natural ability to metabolize alcohol

I, Emil Chiaberi, am authorized to certify this notification on behalf of Spirit Sciences USA, Inc. I certify that the information presented and contained in this notification is complete and accurate and that Spirit Sciences USA, Inc. has substantiation that each statement of nutritional support is truthful and not misleading.

Please review the above information and submit this notification to the Spirit Sciences USA, Inc. file. Should you have any questions or concerns, please contact me at (310) 568-1030 x202.

Respectfully submitted,

Emil Chiaberi

Chief Executive Officer Spirit Sciences USA, Inc.

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